

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/DK2005/000027

International filing date (day/month/year)
17.01.2005

Priority date (day/month/year)
16.01.2004

International Patent Classification (IPC) or both national classification and IPC
G01N21/78, G01N21/25, G01N21/27, G01N33/04

Applicant
CHR. HANSEN AS

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2005/000027

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 16,21-23,27,39

because:

- ☒ the said international application, or the said claims Nos. 16,21-23,27,39 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☒ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2005/000027

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15,17-20,24-26,28-38,42,43,45
	No: Claims	40-44
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15,17-20,24-26,28-38,40-45
Industrial applicability (IA)	Yes: Claims	1-15,17-20,24-26,28-38,40-45
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

- 1.1 **Claims 16, 21-23 and 27** relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(v) PCT.

Claim 39 contains references to the description and the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

- 1.2 Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

- 2 Reference is made to the following documents:

D1 : EP 0 301 699 A (UNIV UTAH) 1 February 1989

D2 : US 2001/039032 A1 (HYMAN JONES M ET AL) 8 November 2001

3 INDEPENDENT CLAIM 1

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.

- 3.2 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parentheses applying to this document):

A method for (..) determination of a biological, chemical or physical property of a plurality of individual samples of a turbid medium (Col. 1 lines 8-12) comprising the steps:

i) arranging said individual samples of the medium comprising a color indicator in an array (Col. 7 lines 8-11 and col. 11 lines 49-55);

ii) allowing said color indicator to interact with said samples (Col. 8 lines 24-27);

iii) individually examining said samples, following said interaction, using a micro-colorimeter (Figure 1 and Col. 15 lines 7-11) to determine the color developed on a surface of said sample (Col. 14 lines 21-35),

iv) to obtain a (..) value representation for said property, said (..) value representation being used for calculating a value for said property (Col. 12 lines 1-5).

- 3.3 The subject-matter of independent claim 1 differs from the disclosure of D1 in that the determination is performed *simultaneously*,

as picture capturing means are provided for capturing a digital image, said digital image being used to obtain a *digital* value representation.

3.4 The problem to be solved by the present invention may therefore be regarded as how to accelerate the analysis of the plurality of samples.

3.5 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The feature to use picture capturing means for capturing a digital image (Paragraph 60 and 113) being used to obtain a digital value representation, is described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the method described in document D1 in order to solve the problem posed.

3.6 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

4 INDEPENDENT CLAIM 40

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 40 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this document):
A system for determining a chemical or physical property of a turbid medium comprising:

- I) a container (240; see paragraph 55) for containing a sample of said medium;
- ii) an indicator to be introduced in said sample, said indicator being adapted to indicate a specific value of said property by a specific color (Paragraphs 85 and 87);
- iii) an incubator (206; see paragraph 42) for supporting said container and incubating said sample contained in said container;
- iv) a scanner (208; see paragraphs 42 and 60) or digital camera for scanning said container, thereby generating an image file recording the color of said sample having reacted with the indicator;
- v) an analyser for analysing said image file and generating data values for image

parameters for said image file and determining the value of said property of said sample from said image parameters (See paragraphs 61-72).

5 INDEPENDENT CLAIM 44

5.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 44 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this document):

A computer program comprising code (paragraph 15) adapted to perform the following actions (See paragraphs 42 and 91; claims 25 and 43) when said program is run in a data processing system:

- i) control of scanning of a container containing a sample;
- ii) generation of an image file of one surface of said container;
- iii) identification of a color of said one surface of said container;
- iv) analysis of said image file and generation of data values for image parameters;
- and
- v) translation of image parameters to a pH value of said sample.

6 DEPENDENT CLAIMS 2-15, 17-20, 24-26, 28-38, 41-43, 45

6.1 Dependent claims 2-15, 17-20, 24-26, 28-33, 41, 43, 45 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).